

Stavrianopoulos et al.
Serial No.: 08/486,070
Filed: June 7, 1995

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Invention Claimed In U.S. Patent Application Serial No. 08/486,070)
- May 30, 2001]



REMARKS

Claims 718-1265 are pending and under examination in this application. No claim changes have been effected by this Communication.

As indicated by the title, the purpose of this Communication is to transmit charts in support of the invention claimed in the present application. The subject matter at hand includes a solid support comprising an array of substrate surfaces, each substrate surface comprising at least one double-stranded nucleic acid fixed or immobilized thereto, as recited in claims 718-799). The subject matter also includes a non-porous solid support comprising an array of substrate surfaces, each substrate surface comprising at least one nucleic acid strand fixed or immobilized thereto, as recited in claims 800-872. As described below, the charts being transmitted herewith are four in number and are attached as Exhibits 1-4.

The first and second "support" charts (Exhibits 1-2) were first presented at the December 5, 2000 interview, and later submitted as Exhibits 2 and 3 to Applicants' March 7, 2001 Amendment Under 37 C.F.R. §1.115. The first and second "support" charts were discussed in two instances in Applicants' March 7, 2001 Amendment. The first instance occurs on page 55, first paragraph, where it is disclosed:

... Applicants' inventive concept can be best understood by viewing two charts which have been prepared from the specification at hand. Attached as Exhibit 2, the first chart shows the interrelationship between the solid support and various other elements or embodiments, including nature of the support material, surface treatments, devices, apparatus and, of course, the array subject matter. List(sic) on the second chart which is attached as Exhibit 3, are citations to the specification which support the various elements, embodiments and relationships.

The second instance occurs on page 60, first full paragraph, where Applicants disclose:

[1] With respect to the array issue, it is important to note that new claims 718-872 are all directed to a solid support comprising an array of substrate surfaces. The fixation or immobilization of nucleic acid to a solid support, including the aforementioned array of substrate

surfaces, is an inventive concept universally disclosed throughout Applicants' original specification. Applicants' invention has spawned innumerable useful applications in nucleic acid technology, including detection, genetic and sequence analysis, and drug screening.

Applicants' inventive concept can be best understood by viewing two charts which have been prepared from the specification at hand. Attached as Exhibit 2, the first chart shows the interrelationship between the solid support and various other elements or embodiments, including nature of the support material, surface treatments, devices, apparatus and, of course, the array subject matter. List on the second chart which is attached as Exhibit 3, are citations to the specification which support the various elements, embodiments and relationships.

[emphasis added]

Both support charts (Exhibits 1 and 2 herewith) were referenced in the Declaration of Dr. Cheryl H. Agris which was submitted as Exhibit A to Applicants' May 8, 2001 Communication.¹ In the last paragraph on page 17 in her Declaration, Dr. Agris refers to both support charts as follows:

A. In Applicants' March 7, 2001 Amendment, two charts were submitted as Exhibits 2 and 3 to that paper. Both charts depicted the nature of Applicants' claimed solid support and its relationship to other elements or sub-elements disclosed in the '070 specification, including the instantly claimed array of substrate surfaces. Both charts are also attached to my Declaration as Exhibits 8 and 9.² As shown in the two charts (Exhibits 8 and 9), the solid support can be porous and non-porous, and transparent or translucent in the case of either. Polymeric materials can be used to construct the porous solid support or the non-porous solid support. In the case of the porous solid supports, such polymeric materials include porous glass, nitrocellulose filters, dextran and treated porous glass. In the case of non-porous solid supports, polymeric materials include dextran, plastic and glass. Plastics can include polystyrene, polyethylene and polypropylene. Treated surfaces include treated plastic and treated glass. The former includes treatment with duodecadiamine (DDA), polylysine (PPL), epoxy resin or glues, ammonium acetate (NH₄OAc) and amino-derivitized. The latter, treated glass, includes treatment with γ -aminopropyltriethoxysilane, coating solution, epoxy resin or glues and ammonium acetate (NH₄OAc).

Two other charts have been prepared in connection with Applicants' claimed invention. In one chart attached as Exhibit 3, Applicants have provided full detail and support in the original specification and original claims for the subject matter of

¹ The full title of Dr. Agris's Declaration is "Declaration Of Dr. Cheryl H. Agris, Attorney At Law (In Support Of The Written Description Of The Invention Claimed In U.S. Patent Application Serial No. 08/486,070)."

claims 718 and 800. Support in the original specification includes disclosure on page 10 (lines 17-20); page 13, line 29, through page 14, line 1; and page 14; (lines 7-26). Other support is found in the Detailed Description (page 15, second paragraph) and Examples 1-3 and 5-6. In the chart (Exhibit 3), the originally filed claims are cited in support of Applicants' claims 718 and 800. The originally filed claims include claims 17, 23 and 21.

In the chart attached as Exhibit 4, there are depicted the species of elements which support Applicants' claimed genus of an "array of substrate surfaces." The chart (Exhibit 4) begins on the upper left side with reference to the September 7, 2000 Office Action in which the subject matter for "glass or plastic arrays having depressions or wells" (shown boxed in red) was deemed to be adequately described in the specification. Underneath that red box is "Support For "Means For Containing A Fluid" (shown boxed in blue) and five separate bullets citing disclosure in support of Applicants' subject matter. These five bullets include the following:

- Apparatus comprising a plurality of devices for containing a fluid, in which at least one such device contains the above-described immobilized polynucleotide sequence, polynucleotide or oligonucleotide probe, . . .
Specification, page 14, lines 21-26
- Conventional apparatus employed in diagnostic laboratories, i.e., plastic or glass wells, tubes, cuvettes or arrangements of wells, tubes or cuvettes.
Specification, page 13, last 2 lines, through page 14, 1st line
- The portion of the device for containing the fluid is desirably a well, a tube, or a cuvette.
Specification, page 14, lines 19-20
- An apparatus comprising a plurality of means for containing a fluid, wherein at least one of said means comprises:
an immobilized polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, . . .
Specification, originally filed claim 23
- Said means for containing a fluid is selected from the group consisting of a well, a tube, and a cuvette.
Specification, originally filed claim 21

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In the upper right side of the chart (Exhibit 4) is the "Support For 'Surfaces' In Examples (shown boxed in green) and brief citations to four examples. The four examples include, of course, Example 2 (" . . . glass surface . . ."); Example 3 (" . . . glass surface . . ."); Example 5 (" . . . plastic surface . . ." or ". . . non-porous plastic surface . . ."); and Example 6 (" . . . glass or polystyrene surfaces . . ." and ". . . surfaces or wells . . .").

Finally, in connection with the last chart (Exhibit 4), a "Composite" claim is given at the lower right side (shown boxed in gray). The composite claim recites:

Glass or plastic arrays having depressions or wells or other surfaces or
being a plurality of devices or means for containing a fluid which are
desirably wells, tubes or cuvettes or an arrangement of wells, tubes or
cuvettes. *Claim reciting all of the species cited*

It should be noted that in her Declaration submitted with Applicants' May 8, 2001 Communication, Dr. Agris also addressed in full detail the issue related to their having disclosed a representative number of species to support the generic subject matter of claims 718 and 800.² The chart (Exhibit 4) provides an illustration of many of Dr. Agris's points in her Declaration.

It is respectfully requested that full consideration be given to each of the four charts (Exhibits 1-4) which are being submitted in order to clarify the nature of Applicants' claimed invention as set forth in claims 718 and 800.

Favorable action is respectfully requested.

* * * * *

² The section of Dr. Agris's Declaration dealing with representative number of species is titled "APPLICANTS HAVE DISCLOSED A REPRESENTATIVE NUMBER OF SPECIES TO SUPPORT THE GENERIC SUBJECT MATTER OF CLAIMS 718 AND 800." The pertinent Subsections C and D are found on pages 18 and 19 of her Declaration.

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SUMMARY AND CONCLUSIONS

Claims 718-1265 continue to be presented for further examination in this application. No changes to the claims have been effected by this Communication, the purpose of which is to present four charts bearing on the written description of Applicants' claimed subject matter.

No fee or fees are believed to be due in connection with this Communication, a Request For An Extension Of Time (3 Months) and authorization for the fee having been previously filed with Applicants' March 7, 2001 Amendment Under 37 C.F.R. §1.115. In the event that any other fee or fees are due, however, authorization is hereby given to charge the amount of any such fee(s) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney request that he be contacted at the number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ronald C. Fedus".

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